

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO PLAINTIFFS: WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' REPLY TO DEFENDANTS' RESPONSE IN OPPOSITION TO
PLAINTIFFS' DAUBERT MOTION TO PRECLUDE
THE TESTIMONY OF JUAN C. FELIX, M.D.**

In further support of the Motion to exclude certain expert testimony proffered by Defendant Ethicon's ("Defendant") expert Juan C. Felix, M.D. ("Dr. Felix"), Plaintiffs state as follows:

I. Dr. Felix's qualifications do not provide support for his opinions regarding the Prolift or TVT mesh.

Ethicon argues that "Dr. Felix is eminently qualified to offer his opinions as an expert pathologist in this case." Def's Resp. at 1. However, this general experience in the field of pathology is not sufficient to support his opinions here. Defendant's argument fails to take into account that Dr. Iakovlev's opinions—the true focus of Dr. Felix's report—are not general in nature, but specific to polypropylene mesh and how it reacts in the human body. Dr. Felix's qualifications do not relate specifically to vaginal mesh. Examining two or three explanted mesh samples per year does not make anyone an expert in polypropylene mesh *or* how it reacts with the human body. None of Dr. Felix's stated qualifications allow him to testify as an expert regarding the characteristics of the Prolift, its clinical pathological correlations, or his critiques of

Dr. Iakovlev. As such, Dr. Felix should not be allowed to offer opinions regarding degradation, mesh contraction and pain –nor should he be permitted to criticize Dr. Iakovlev’s opinions on these subjects.

II. Dr. Felix’s methodology is not sufficient to support his opinions

a. Dr. Felix provides no methodology for his clinical review of explanted mesh

Glaringly absent from Defendant’s response to Plaintiff’s arguments about the unreliable nature of Dr. Felix’s clinical review of explanted mesh samples is any sort of discussion of the specifics of Dr. Felix’s methodology, itself. Indeed, there is no discussion of how he selected the mesh or what he did in order to arrive at his conclusions, nor is there any real attempt to support those opinions. There is no claim that he performed any specific research on how mesh reacts in the human body, or performed any studied on mesh and post-operative pain. As the proponent of Dr. Felix’s testimony, it is Defendant’s burden to provide that type of information.¹

Ethicon points out that Dr. Felix claims to have reviewed over 50 mesh samples over the course of his career. Def’s Resp. at 4. However, even when faced with Plaintiffs’ *Daubert* motion, neither Ethicon, nor Dr. Felix has done anything to explain the protocol or criteria for that review. Furthermore, Ethicon does not try to contest the fact that his opinions are based entirely on his current recollection of those mesh samples—most of which were explanted in or around the year 2000—because Dr. Felix admitted that he did not review any of the samples since the time they were explanted. Ex. A, at 60.

Ethicon asserts that Dr. Felix is not offering “specific opinions about the meshes he has reviewed during his more than 22 years of experience.” Def’s Resp. at 4-5. Yet in his report, Dr. Felix specifically states that he bases his opinions on his review of these meshes. Ex. B, at 9; Ex.

¹ Defendant has the burden to “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 601 (S.D.W.V. 2013).

C, at 9. And, he seeks to offer specific opinions about what he observed in those samples; stating:

In my experience as a pathologist examining explanted mesh specimens, the findings in cases where the patient had no symptoms of pain were identical to the findings described by Dr. Iakovlev”

Id. at 9.

Indeed, Defendant’s own brief confirms that Dr. Felix seeks to compare the contents of the slides at issue in this case with the contents of the slides that he previously reviewed in his clinical practice. Def’s Resp. at 12. In short, contrary to Defendant’s assertion, Dr. Felix *does* seek to offer specific opinions regarding meshes not at issue in this case—he seeks to offer opinions regarding what those mesh samples contained (or did not contain).

b. Defendants do not demonstrate (or even assert) that Dr. Felix conducted a literature review sufficient to support his opinions

Plaintiffs called into question Dr. Felix’s review of the applicable literature, because if he has not studied issues such as degradation, contraction and pain in his clinical practice, then he must have conducted a sufficient literature review in order to make his opinions on those topics scientifically reliable. As discussed in Plaintiffs’ opening brief, he did not.

Ethicon asserts that Plaintiffs “simply ignore” “Dr. Felix’s reliance” on the scientific authority contained within his report and reliance list. Def’s Resp. at 6. However, it is not the Plaintiffs who ignore the scientific authority contained in his report, but Dr. Felix. For example, during deposition Dr. Felix was asked the following questions:

Q. Okay. Let me mark your reliance list for Ms. Ruiz Number 8.

Q. You recognize that document?

A. Yes.

Q. Is this a document created by counsel for Ethicon and Johnson & Johnson?

A. Yes.

Ex. D at 57:21-58:6.

Q. There is a section as well with regard to documents that you were provided a couple pages back. Do you see that?

A. Where is says, "Other materials"?

Q. "Document Description," right after the medical literature.

A. Yes.

Q. There were documents selected by Ethicon's lawyers to provide to you, internal Ethicon documents; is that right?

A. Correct.

Id. at 58:24-59:9

Q. The deposition of Dr. Barbolt, did you review that deposition?

A. I don't recall.

Q. Thomas A Barbolt?

A. I have to look it up to refresh my memory because I did read some deposition here.

Q. This would have been an Ethicon corporate person. He's not a treating physician.

A. I don't recall.

Q. It's fair to say, since you didn't review all of the deposition transcripts, that this reliance list contains things that you actually didn't rely on; fair?

A. You're correct.

Id. at 60:18-61:8.²

Dr. Felix's answers to these questions make it clear that the documents contained within his reliance list were those provided to him by Ethicon. Obviously the Defendant was fully aware of this which is why Defense Counsel did not object to Plaintiff's Counsel's statement, "that Dr. Felix's 'reliance list was created by counsel for Ethicon and is incomplete or inaccurate.'" Dr. Felix's opinions are not rendered scientifically reliable based on his experience alone; therefore, Ethicon needs to demonstrate that he supplemented his knowledge with a sufficient literature review. Defendant has not attempted to do so.

² Dr. Thomas Barbolt was a former scientist employed by Ethicon who was deposed as a 30(b)(6) witness who admitted that the PROLENE polypropylene material used to manufacture the Prolift and TVT device undergoes *in vivo* surface degradation.

III. Opinions based on Dr. Felix's reliance of Defendant's expert Dr. Steven MacLean must be excluded

Plaintiff does not "suggest" that Dr. Felix relies on Dr. Steven MacLean's findings in formulating his opinion; Dr. Felix states that he relies on Dr. MacLean's findings in formulating his opinions. *See* Ex. D at 11:22-12:7. Plaintiffs adopt and incorporate the arguments made in Plaintiff's *Motion and Memorandum to Exclude the Opinions and Testimony of the Defendant Ethicon, Inc's Expert Steven MacLean*, and *Plaintiffs' Reply to Defendant's Response in Opposition to Plaintiffs' Motion and Memorandum to Exclude the Opinions and Testimony of Defendant Ethicon, Inc's Expert Steven Maclean*. *See* Ex. E-F. Furthermore, Plaintiffs adopt and incorporate the arguments made in *Plaintiffs' Daubert Motion to Exclude the Opinions and Testimony of Dr. Steven MacLean* filed May 14, 2016. *See* Ex. G. Based on the arguments made in the aforementioned documents, Dr. Felix's opinions based on reliance of Dr. Steven MacLean's finding should be excluded.

IV. Cytotoxicity

Defendant effectively admits that Dr. Felix's opinions regarding cytotoxicity and particle loss are the very type of "I have not seen it" testimony that this Court has repeatedly excluded. The fact that Dr. Felix has not happened to notice cytotoxicity or particle loss with respect to the mesh in his own practice is not sufficient to render opinion on the subject.³

³ *Tyree*, 2014 U.S. Dist. LEXIS 155138, *183-85 ("[a]bsence of evidence is not evidence of absence").

Dated: May 16, 2016

Respectfully submitted,

/s/Bryan F. Aylstock

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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